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IP DEPARTMENT OF PIPER RUDNICK LLP
ONE LIBERTY PLACE, SUITE 4900
1650 MARKET ST
PHILADELPHIA, PA 19103

EXAMINER

KERR, KATHLEEN M

ART UNIT PAPER NUMBER

1652

DATE MAILED: 12/10/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/805,681

Applicant(s)

PHADTARE ET AL.

Examiner

Kathleen M Kerr

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 November 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 16-20 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 16-20 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 11/8/04.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Application Status

1. In response to the previous Office action on the merits, a non-Final rejection (mailed on November 26, 2003), Applicants filed an amendment received on May 14, 2004. Said amendment cancelled Claims 7, 8, 10, 12, and 15 and added new Claims 16-20. All the new claims are drawn to the elected invention (see restriction requirement in the Office action mailed November 26, 2003). Claims 16-20 will be examined herein.

Possible Rejoinder

2. The Examiner notes that previously filed claims of processes may be subject to rejoinder as noted in the restriction requirement in the office action mailed November 26, 2003.

Priority

3. As previously noted, the instant application is granted the benefit of priority for the U.S. Provisional Application No. 60/228,727 filed on August 29, 2000. The Examiner notes that the protein sequence of the claimed DHCP efflux protein is disclosed in said provisional application, but not the encoding DNA sequence itself as being examined herein.

Drawings

4. As previously noted, the drawings have been approved by the Draftsmen and are, therefore, entered as formal drawings acceptable for publication upon the identification of allowable subject matter.

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Withdrawn - Claim Rejections - 35 U.S.C. § 112

5. Previous rejection of Claims 7, 8, 10, and 12 under 35 U.S.C. § 112, second paragraph, as being indefinite for the phrase “the amino acid sequence (SEQW ID NO:3)” is withdrawn by virtue of Applicant’s cancellation of said claims and lack of use of this phrase in the newly pending claims.

6. Previous rejection of Claim 8 under 35 U.S.C. § 112, first paragraph, written description, is withdrawn by virtue of Applicant’s cancellation of said claim.

Withdrawn - Claim Rejections - 35 U.S.C. § 102

7. Previous rejection of Claims 7-8 under 35 U.S.C. § 102(b) as being anticipated by Blattner *et al.* is withdrawn by virtue of Applicant’s cancellation of said claims.

Withdrawn - Claim Rejections - 35 U.S.C. § 103

8. Previous rejection of Claims 10 and 12 under 35 U.S.C. § 103(a) as being unpatentable over Blattner *et al.* in view of Weickert *et al.* is withdrawn by virtue of Applicant’s cancellation of said claims.

NEW ISSUES

Claim Rejections - 35 U.S.C. § 112

The following is a quotation of the second paragraph of 35 U.S.C. § 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

9. Claims 16-19 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. With respect to Claims 16-18, the phrases “a disrupted pur gene” and similar phrases with a ydhC gene and a ydhB gene are unclear. The adjective “disrupted” is unclear as to what extent or what exactly constitutes disruption. Must any portion of a pur gene remain? If so, how much?

Moreover, with respect to Claims 16-19, what is the nature of “a pur gene”, “a ydhC gene”, and “a ydhB gene”? Only a single example of each gene from *E. coli* is taught in the instant specification. Must these genes encode something specific? Their identity is particularly unclear with random names like ydhC - such naming often occurs in genome sequencing when function cannot be assigned. If a gene is “named” something else, and it is disrupted, would it read on the claim? Clarification is required.

The following is a quotation of the first paragraph of 35 U.S.C. § 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

10. Claims 16-19 are rejected under 35 U.S.C. § 112, first paragraph, new matter, as failing to comply with the written description requirement. The claim(s) contains subject matter which

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was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The concept of genera of any plasmid encoding SEQ ID NO:3 is envisioned by the specification (see for example on page 3). However, the instant claims are drawn to sub-genera of this concept wherein (1) a particular gene must also be disrupted on said plasmid or (2) the plasmid must be free of other, particular genes.

The specification contains species of Claim 16 in the form of pSP002, pSP006, and pSP007 (depending on the definition of “disrupted”); however, the genus of Claim 16 is not envisioned.

The specification does not contain any species or description of the species of Claim 17.

The specification contains species of Claim 18 in the form of pSP003, pSP006, and pSP007 (depending on the definition of “disrupted”); however, the genus of Claim 18 is not envisioned.

The specification contains a species of Claim 19 in the form of pSP007; however, the genus of Claim 19 is not envisioned.

Applicant must cancel the alleged new matter or cite clear support (page and line number) where the genera of the instant claims are envisioned in the specification as originally filed.

11. Claim 20 is rejected under 35 U.S.C. § 112, first paragraph, enabling deposit, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. To practice the instant methods, one of skill in the art is required to use

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pSP007. The instant specification contains no deposit information; the requirements to enable such a deposit have not been fully met by the instant application. To enable the instant claims by enabling the deposit of pSP007, the following items are required in the specification: (1) the accession number assigned by the depository, (2) the date of deposit, (3) a brief description of the deposit, (4) the name and full address of the depository (37 C.F.R. § 1.801 - 1.809), and (5) the record must also contain a statement certifying that all restrictions on accessibility to said deposit be irrevocably removed by Applicant upon the granting of the patent (see M.P.E.P. § 2404.01); this statement may be certified by Applicants or Applicants' representative.

Claim Rejections - 35 U.S.C. § 103

The following is a quotation of 35 U.S.C. § 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

12. Claim 19 is rejected under 35 U.S.C. § 103(a) as being unpatentable over Blattner *et al.* (Science, 1997) in view of Weickert *et al.* The instant claims are drawn to multicopy plasmids containing the *dep* gene from *E. coli* and not containing particular other genes.

Blattner *et al.* teach an open reading frame of DNA from the *E. coli* genome encoding a putative transport protein from 4627 bp to 5838 bp (see GenBank Accession Number AE000261 for numbering). This DNA is identical to SEQ ID NO:2 (see previously attached alignment). This DNA also has the inherent property of encoding a protein conferring DHCP resistance when present in multiple copies. The Examiner notes that on page 10 of the instant specification, the

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GenBank reference noted above is admitted as prior art. While Blattner *et al.* teach sequencing techniques using plasmids, no expression plasmids are taught for the individual open reading frames as disclosed.

Weickert *et al.* teach the heterologous expression of proteins in *E. coli* using multicopy plasmids to achieve good protein production (see Table 1, page 495).

It would have been obvious to one of ordinary skill in the art to combine the teachings of Blattner *et al.* and Weickert *et al.* to make multicopy plasmids for expression of the open reading frames disclosed by Blattner *et al.* in bacterial host cells because Blattner *et al.* specifically suggest “analysis of biochemical and catalytic properties of the expressed proteins” (see page 1461, left column) and Weickert *et al.* specifically teach multicopy plasmids as a technique for optimizing heterologous protein overproduction, which overproduction is required for protein purification and activity assays. One would have been motivated to combine the above teachings to overproduce the encoded protein, which Blattner *et al.* describe as a putative transport membrane protein, to attribute a specific function to the protein – a common practice in the art.

Summary of Pending Issues

13. The following is a summary of the issues pending in the instant application:
- a) Claims 16-19 stand rejected under 35 U.S.C. § 112, second paragraph, as being indefinite.
 - b) Claims 16-19 stand rejected under 35 U.S.C. § 112, first paragraph, new matter.
 - c) Claim 20 stands rejected under 35 U.S.C. § 112, first paragraph, enabling deposit.
 - d) Claim 19 stands rejected under 35 U.S.C. § 103(a) as being unpatentable over Blattner *et al.* (Science, 1997) in view of Weickert *et al.*

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Conclusion

14. Claims 16-20 are not allowed for the reasons identified in the numbered sections of this Office action. Applicants must respond to the objections/rejections in each of the numbered sections in this Office action to be fully responsive in prosecution.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See M.P.E.P. § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 C.F.R. § 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 C.F.R. § 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kathleen M Kerr whose telephone number is (571) 272-0931. The examiner can normally be reached on Monday through Friday, from 9:00am to 6pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathupura Achutamurthy can be reached on (571) 272-0928. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Kathleen M Kerr
Primary Examiner
Art Unit 1652

December 7, 2004